



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0748]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Cover Sheet; Form FDA 3794

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning collection of information using Form FDA 3794 entitled “Generic Drug User Fee Cover Sheet.”

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Drug User Fee Cover Sheet; Form FDA 3794--

(OMB Control Number 0910-New)

On July 9, 2012, the Generic Drug User Fee Act (GDUFA) (Public Law 112-144, Title 111) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug manufacturers pay user fees to finance critical and measurable program enhancements. The user fees required by GDUFA are as follows: A one-time fee for original abbreviated new drug applications (ANDAs) pending on October 1, 2012 (also known as backlog applications); fees for type II active pharmaceutical ingredient (API) and final dosage form (FDF) facilities; fees for new ANDAs and prior approval supplements (PASs); and a one-time fee for drug master files (DMFs).

The purpose of this notice is to solicit feedback on the collection of information in an electronic form used to calculate and pay generic drug user fees. Proposed Form FDA 3794, the Generic Drug User Fee Cover Sheet, requests the minimum necessary information to determine if a person has satisfied all relevant user fee obligations. The proposed form is modeled on other FDA user fee cover sheets, including Form FDA 3397, the Prescription Drug User Fee Act Cover Sheet. The information collected would be used by the FDA to initiate the administrative screening of generic drug submissions and DMFs, support the inspection of generic drug facilities, and otherwise support the generic drug program. A copy of the proposed form will be available in the docket for this notice.

Respondents to this proposed collection of information would be potential or actual generic application holders and/or related manufacturers (manufacturers of FDF and/or APIs). Companies with multiple applications will submit a cover sheet for each application and facility. Based on FDA's database of application holders and related manufacturers, we estimate that 500 companies would submit a total of 3,850 coversheets annually to pay for application and facility user fees. FDA estimates that the 3,850 annual cover sheet responses would break down as follows¹: 2,000 facilities fees, 750 ANDAs, 750 PASs, and 350 Type II API DMFs. We also estimate that the one-time backlog fee would affect 350 application owners sponsoring 2,700 applications. The estimated hours per response are based on FDA's past experience with other submissions, and range from approximately 0.1 to 0.5 hours. The hours per response are estimated at the upper end of the range to be conservative.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3794 ²	500	7.7	3,850	0.5	1,925

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

²For all applicable applications and fees except for the backlog fee.

The backlog fee is a one-time fee. The Agency expects the majority of these fees to be received in the first year only. The estimated reporting burden for the backlog fee is shown in table 2 of this document.

¹These estimates are based on conversations between the Agency and representatives of regulated industry during the generic drug user fee negotiations.

Table 2.--Estimated One-Time Annual Reporting Burden¹

Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3794 ²	350	7.7	2,700	0.5	1,350

¹There are no capital costs or operating maintenance costs associated with this collection of information.

²For backlog fee.

Dated: July 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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